

## REMARKS

Applicant has amended claim 48. Claims 24 and 26-48 are pending in this application.

In the office action, the Examiner indicated that claims 27-34 and 37-43 would be allowable if they are rewritten in independent form. Applicant gratefully acknowledges the Examiner's indication of allowable subject matter.

The Examiner also maintained the final rejection of claims 24-26, 35, 36 and 44 under 35 U.S.C. Section 102(b) as being anticipated by Teirstein (U.S. Patent No. 5,779,666). Applicant traverses the rejection.

The present application is related to RE38,074, issued April 8, 2003, which is a reissue of U.S. Patent No. 6,315,762. The reissue application was examined by Examiner Michael Thompson and Anhtuan Nguyen. All independent claims of the present application are drawn along the lines of reissued claim 9 in the parent reissue application with respect to how the valves co-operate with each other to provide a safe operation of the system.

As discussed in Applicant's previous response, an important feature of Applicants' invention is the manner in which the two one-way valves 19 and 18 operate to assure proper and safe operation of the system. When the pump 13 is drawing in contrast medium from the bag 11, it is important that the valve 19 automatically open and the valve 18 automatically close. The contrast medium will flow into the pump and nothing will flow upstream from the connecting tube 22. Thus nothing will flow upstream from the vascular system to which the apparatus is connected.

It is further important that when the pump 13 delivers the contrast medium from the pump to the vascular system, that the valve 19 automatically close. The contrast medium is not returned to the bag 11 and the valve 18 will automatically open so that the contrast medium can be delivered through the connecting tubular member 22 to the vascular system.

As persons of ordinary skill in the art will appreciate, it is particularly advantageous that these two valves 19 and 18 automatically open and close in response to the differential pressures to which they are subjected so that this operation proceeds with

assurance and with safety. Therefore, no error can be made by a human operator in opening or closing any valves. In order for this objective to be met and the functions that are provided by these valves 19 and 18 to occur, there should be no ports other than the ports 24 and 27 that are controlled by the valves 19 and 18 which are in communication with the inlet-outlet port 25 to which the pump 13 is connected.

If there are any other ports in the manifold defined by the inlet port 24 (controlled by valve 19), the outlet port 27 (controlled by valve 18) and the inlet-outlet port 25 (connected to the pump 13) an automatic, safe and assured system would not function properly.

All independent claims recite this automatic valve feature. For example, claim 24 recites:

the delivering step including: suctioning at said first inlet-outlet port by the pump to cause said first one-way valve to automatically open, allowing flow of contrast medium from said bag into the pump, and to cause said second one-way valve to automatically close, preventing fluid flow upstream from said connecting tubular member into the pump, and

exerting positive pressure at said first inlet-outlet port from the pump to cause said second one-way valve to automatically open, allowing fluid flow from said pump into said tubular member, and to cause said first one-way valve to automatically close, preventing upstream fluid flow to the source.

By contrast, the valves 44, 46 of Teirstein are coupled to the manifold 16 and are in addition to the inlet valve 42 and outlet port 48 (see col. 4, lines 58-64).

These multiple valves 42, 44, 46 and 48 are manual valves that must be operated by hand during the purge operation and during delivery of the contrast medium. Teirstein even admits that the purging operation is a very time consuming operation precisely because all of the valves must be manually adjusted (See col. 5, lines 5-25). More important than the time consuming nature, however, the manual nature of the Teirstein system can be very dangerous when delivering a pressurized contrast media such as CO<sub>2</sub> because one mistake in adjusting the valves can cause the dumping of excess pressurized contrast media to the patient. As disclosed in the background section of the present application at page 2, lines 11-15, liters of CO<sub>2</sub> can be delivered to the patient in less than

a minute due to the high pressure of CO<sub>2</sub>, which could be fatal. Teirstein neither teaches nor suggests an automatic contrast media delivery as recited in claim 24.

On page 3 of the Office Action, the Examiner asserted that:

A. "Automatic" is defined as operating in a manner essentially independent of external influence or control; and

B. col. 2, lines 60-67, col. 3, lines 1-4 and 29-47, and col. 5, lines 1-4 of Teirstein disclose the automatic activation of the valves as claimed. Applicant respectfully disagrees.

First, the sections that the Examiner refers to above do not relate to the valves attached to the manifold 16 in Teirstein. Rather, those sections refer to a completely different part called a holding chamber 14 to which the one-way valves 36 and 58 are attached. The holding chamber 14 of Teirstein is not equivalent to the "dual check valve" of the present invention. Rather, the manifold 16 is equivalent to the dual check valve as claimed.

Second, even if those sections relate to the valves 42-48 attached to the manifold 16 and even if the valves 42-48 are considered to be one-way valves, Teirstein still does not anticipate the invention of claim 24 because claim 24 requires a closed system where the drawing step includes "to cause said second one-way valve to automatically close, preventing fluid flow upstream from said connecting tubular member into the pump". In Teirstein, on the other hand, when the syringe is pulled to suck the contrast media from the holding chamber 14, the low pressure inside the manifold 16 will cause the one-way valves at valves 44 and 46 to open which will suck in air or whatever source is connected to those valves. In other words, Teirstein allows "fluid flow upstream" from whatever source is connected to the valves 44-46 which would contaminate the close system of the present invention.

For the similar reasons as discussed above with respect to claim 24, applicants submit that independent claims 35, 45 and 48 are also patentable.

In claim 48, Applicant has emphasized that the first and second one-way valves open and close in automatic response to the drawing and exerting steps.

Dependent claims 26, 36, 44 and 46-47 are also patentable by virtue of their dependency from independent parent claims 24, 35 and 45.

Based upon the above amendments and remarks, applicants respectfully request reconsideration of this application and its early allowance. Should the Examiner feel that a telephone conference with applicants' attorney would expedite prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,

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